REMARKS

Applicant has received and carefully reviewed the Final Office Action mailed on March 18, 2008, prior to preparing this response. Currently, claims 11-21 are pending in the application, wherein claims 11-21 have been rejected. Favorable consideration of the following remarks is respectfully requested.

Rejections Under 35 U.S.C. §103

Claims 11-17 were rejected under 35 U.S.C. 103(a) as being unpatentable over Preissman et al. (U.S. Patent No. 5,728,063) in view of Fontirroche et al. (U.S. Patent No. 5,538,510), and Ross et al. (U.S. Patent No. 5,395,866). This rejection is respectfully traversed.

Claim 11 recites:

> A catheter comprising: a first catheter tube having at least two superposed layers of materials, including an inner layer and an outer layer, secured together with a polymeric mediator layer adhered to both the inner layer and the outer layer, and with mechanical properties differing from one another, a lumen in the first catheter tube, and a balloon sealingly surrounding the first catheter tube, whereby the inner layer comprises high-density polyethylene and forms the lumen, and the outer layer comprises a polymer and forms an outer surface of the first catheter tube, wherein the first catheter tube includes a distal end and the outer layer extends to the distal end of the first catheter tube.

Emphasis added.

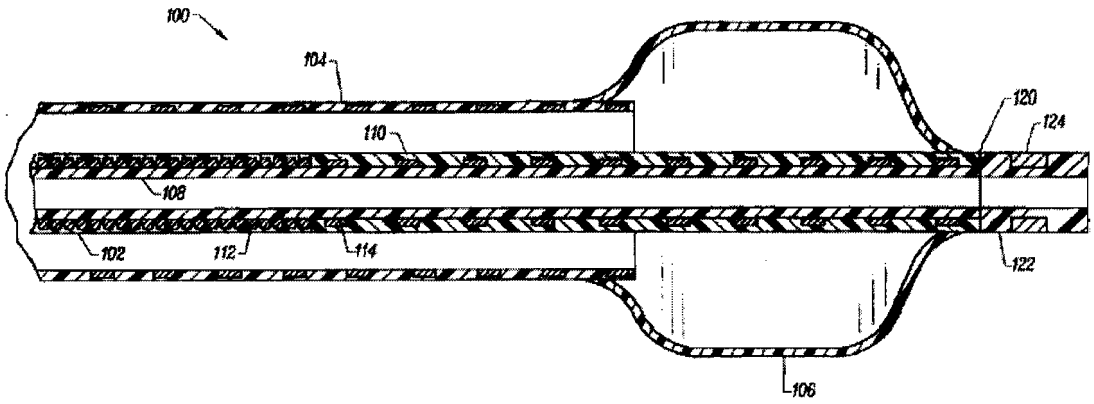
In formulating the rejection of claim 11, it appears that the claimed "first catheter tube" is being equated to the inner catheter 102; the claimed "inner layer" is being equated to the inner tubular member 108; the claimed "outer layer" is being equated to the soft outer layer 110; and the claimed "mediator layer" is being equated to the first and second reinforcement layers 112, 114 of Preissman.

Applicant respectfully asserts that at no point does Preissman teach that the first and/or second reinforcement layers 112, 114 (equated to the claimed mediator layer) is adhered to both the inner tubular member 108 (equated to the claimed inner layer) and the outer layer 110 (equated to the claimed outer layer).

In attempting to meet these claim limitations, it appears as though the Examiner is attempting to rely on the passage at column 7, lines 11-14 of Preissman et al. Namely, it was asserted in the Office Action that "the inner tubular members as a laminate structure comprising

outer layer and inner layer or coating, see col. 7, lines 7-14, therefore, the media layer 112, 114 adhered to inner and outer layer." Applicant respectfully asserts that this passage does not disclose that which is currently claimed.

Beginning at the top of column 7, Preissman et al. indicate that the preferred catheter construction includes an inner tubular member defining an inner lumen, a braided reinforcement layer formed directly over the inner tubular member, and a soft outer layer formed over the braided reinforcement layer. This construction as illustrated in FIG. 4 of Preissman et al. is reproduced below, wherein the inner tubular member is referenced as 108, the reinforcement layer is referenced as 112, 114, and the soft outer layer is referenced as 110.



Again referring to the passage identified in the Office Action, the passage recites:

> It would also be possible to form the inner tubular members as a laminate structure comprising a non-lubricious outer layer and an inner lubricious layer or coating.

Thus, the cited passage of Preissman et al. indicate that it is the inner tubular member 108 (equated to the claimed inner layer) which may be a laminate structure having an outer layer and an inner lubricious layer. Therefore, Preissman et al. teach that the inner tubular member 108 may include an outer layer and an inner layer. In such an embodiment, the braided reinforcement layer 112, 114 would be formed directly over the outer layer of the inner tubular member 108. At no point does this passage of Preissman et al. indicate that the braided reinforcement layer 112, 114 (which is being equated to the claimed mediator layer) is "adhered to both the inner layer and the outer layer" securing the inner layer and the outer layer together, as recited in claim 11.

Applicant respectfully disagrees with the statement in the Office Action that "Preissman clearly discloses that the inner tubular members as a laminate structure comprising: an outer layer 110 and an inner layer 108. While the middle layer/reinforcement layer 112, 114 disposed in between the inner layer 108 and the outer layer 110." See Final Office Action, March 18, 2008 at page 4. As addressed above, the cited passage of Preissman et al. indicates that it is the inner tubular member 108 which may be a laminate structure having an inner layer and an outer layer. This is very different from the Examiner's erroneous assertion that the laminate structure comprises the outer layer 110 and the inner tubular member 108 with the middle layer/reinforcement layer 112, 114 disposed therebetween. Both the reinforcement layer 112, 114 and the outer layer 110 of Preissman et al. would be located exterior to the outer layer of any laminate structure taught in Preissman et al., and thus would not be a part of the laminate structure.

In the event that the Examiner is attempting to rely on the inner layer and the outer layer of the laminate structure of the inner tubular member taught in Preissman et al. at column 7, lines 7-14 as meeting the limitations of claim 11 in which the claimed inner layer and outer layer are secured together with a polymeric mediator layer adhered to both the inner layer and the outer layer, Applicant respectfully disagrees. Preissman et al. fail to disclose the inclusion of a mediator layer between the inner layer and the outer layer of the laminate structure adhered to both the inner layer and the outer layer. It is further noted that claim 11 recites that the claimed inner layer "forms the lumen" in the first catheter tube, and the claimed outer layer "forms an outer surface" of the first catheter tube. Thus, if the outer layer of the laminate structure of the inner tubular member of Preissman et al. is being equated to the claimed outer layer, it is noted that the outer layer of the laminate structure does not form an outer surface of the first catheter tube. Instead, the braided reinforcement layers 112, 114 are formed over the outer layer of the laminate structure of the inner tubular member 108, and the soft outer layer 110 is then formed over the braided reinforcement layers 112, 114. Thus, it is the soft outer layer 110 which forms an outer surface of the inner catheter 102 taught in Preissman et al.

The teachings of Fontirroche et al. and Ross fail to remedy the noted shortcomings of Preissman et al. necessary to establish a *prima facie* case of obviousness. For at least the reasons stated above, each and every limitation of claim 11 is not taught or suggested by the cited prior art. Thus, claim 11 is believed to be in condition for allowance. Claims 12-15, which depend

from claim 11 and include additional limitations, are also believed to be in condition for allowance. Withdrawal of the rejection is respectfully requested.

Claim 16 recites:

> A catheter comprising: a catheter tube having at least two superposed layers of materials, including an inner layer and an outer layer, secured together and with mechanical properties differing from one another, a guidewire lumen in the catheter tube for the sliding fit of a guidewire, and a balloon with a distal end sealingly surrounding the outer layer of the catheter tube, wherein the inner layer comprises high-density polyethylene and forms the guidewire lumen, and the outer layer comprises a polyamide and forms an outer surface of the catheter tube, and wherein the catheter tube further comprises a mediator layer providing adhesive anchorage between the inner layer and the outer layer.

Emphasis added.

It appears as though the teachings of Preissman et al. are being primarily relied on in formulating the rejection of claim 16 as teaching the various components of the claimed catheter of claim 16, with the disclosures of Fontirroche et al. and Ross being relied on as disclosing specific material selection for the inner layer and a reinforcement layer. For similar reasons stated above, the teachings of the cited references fail to teach all the claimed limitations of claim 16.

Namely, the cited references fail to teach a mediator layer providing adhesive anchorage between the inner layer and the outer layer of the claimed catheter. At no point does the passage of Preissman et al. indicating the inner tubular member may be a laminate structure, which was cited in the Office Action, indicate that the braided reinforcement layer 112, 114 (which is being equated to the claimed mediator layer) provides "adhesive anchorage between the inner layer and the outer layer" securing the inner layer and the outer layer together, as recited in claim 16.

For at least the reasons stated above, each and every limitation of claim 16 is not taught or suggested by the cited prior art. Thus, claim 16 is believed to be in condition for allowance. Claim 17, which depends from claim 16 and includes additional limitations, is also believed to be in condition for allowance. Withdrawal of the rejection is respectfully requested.

Claims 18-21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Preissman et al. (U.S. Patent No. 5,728,063) in view of Gold et al. (U.S. Patent No. 4,636,346). This rejection is respectfully traversed.

Each of claims 18 and 20 recites in part "a middle layer disposed between the outermost layer and the innermost layer and affixing the outermost layer to the innermost layer." In attempting to equate elements of the catheter of Preissman et al. with those recited in claims 18 and 20, it appears as though the inner tubular member 108 would be required to represent the claimed innermost layer, and the soft outer layer 110 would be required to represent the claimed outermost layer, if at all. With this understanding, Preissman et al. fail to teach a middle layer as claimed which affixes the soft outer layer 110 to the inner tubular member 108.

It appears as though the Examiner has consulted www.answers.com for answers to the meaning of "affix", which the Examiner indicated is defined as "to secure to something"; "attach"; or "to join one thing to another: connect, coupled". In view of these definitions of "affix", Applicant maintains that the cited prior art does not teach the catheter of claims 18 or 20. Namely, the reinforcement layer 112, 114 (which is equated to the claimed middle layer) does not affix (e.g., secure, attach, join, connect, and/or couple) the soft outer layer 110 to the inner tubular member 108.

"In construing claim terms, the general meanings gleaned from reference sources, such as dictionaries, must always be compared against the use of the terms in context, and the intrinsic record must always be consulted to identify which of the different possible dictionary meanings is most consistent with the use of the words by the inventor." M.P.E.P. §2111.01 III, citing *ACTV, Inc. v. The Walt Disney Company*, 346 F.3d 1082, 1092, 68 USPQ2d 1516, 1524 (Fed. Cir. 2003).

As discussed throughout the present application, the presence of the middle layer between the innermost layer and the outermost layer is to insure strong adhesive anchorage between the innermost layer and the outermost layer, regardless of the ability of the innermost layer to be adhered to the outermost layer directly. Thus, the inner and outer layers may be chosen for their most appropriate mechanical characteristics rather than their capacity to adhere to one another. See Specification, at page 3, lines 20-22. The middle layer thus can be chosen to adhere to each of the innermost layer and the outermost layer, affixing the innermost layer to the outermost layer with a strong bond. Because the middle layer affixes the outermost layer to the innermost layer, the risk of separation of the outermost layer from the innermost layer is minimized.

Regarding the teachings of Preissman et al., the reinforcement layer 112 or 114 is held in contact with the inner tubular member 108 by forming the soft outer layer 110 over the braided reinforcement layer. Thus, the reinforcement layer 112 or 114 does not contribute to affixing the inner tubular member 108 to the soft outer layer 110 to help prevent de-lamination of the soft outer layer 110 from the inner tubular member 108. The reinforcement layer 112 or 114 is present simply to provide greater stiffness and column strength to portions of the catheter body. See Preissman et al., at column 10, lines 44-49.

Gold, which the Examiner relies on as teaching a tube comprising an outermost layer having a high coefficient of friction and an innermost layer having a low coefficient of friction, fails to remedy the shortcomings of Preissman et al.

For at least the reasons stated above, claims 18 and 20 are believed patentable over the cited references, as a *prima facie* case of obviousness has not been established regarding either claim 18 or claim 20. Claims 19 and 21, which depend from one of claim 18 and 20 and include additional limitations, are also believed patentable over the cited references. Withdrawal of the rejection is respectfully requested.

CONCLUSION

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By his Attorney,

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